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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/316,313	05/21/1999	RAM PRATAP	U-012254-3	7625

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/316,313

Applicant(s)

PRATAP ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-19 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 11-19, 22 are pending. Claim 21 has been canceled according to the amendment filed on 7-23-2001. Claim 20 has been canceled according to the amendment filed on 10-15-2002.

#### *Claim Rejections - 35 USC § 102*

2. The rejection for Claims 11-19 under 35 U.S.C. 102(b) as being anticipated by Paliwal (PTO-1449) is maintained for reasons of record. The rejection is applicable to new claim 22.

Applicant contends that Carson (submitted with the response) teaches that ‘studies of radical cure with prevention of relapses causal prophylaxis, and sporontocidal and gametocytocidal effects must be considered separately from each other, even for the same anti-malarial drug’, therefore it is incorrect to assume a particular activity is intrinsic in a compound.

While the anti-malarial compound may have different effects at different stages of the malarial life cycle, the different activities are inherent within the compound. The different modes of action as recited in the instant fail to set a demarcation from the method of the prior art. The court holds that claims directed to mediating a biological pathway are devoid identifiable utility and are therefore not useful. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility. Utility is one of three basic requirements for patentable invention, absent which patent protection is impossible. If the invention fails to achieve the advantage over the prior art asserted by the specification, it is not useful as required by 35 USC 101. *Splendor Form Brassiere, Inc. v Rapid-American Corp.* 187 USPQ 158 (CCPA 1975). In the instant case, the biological pathway, such as blocking the malarial oocyst development as recited in claim 11, is patentable only because it is inexorably linked to the treatment of malaria. Paliwal’s method of treating malaria in an animal afflicted with malaria with the CDR1 compound in an anti-malarial effective amount is identical to the instant method wherein the same compound is administered to the same subject. Paliwal’s method would inherently block the malarial oocyst development as recited in the instant claim 11, combat malaria hypnozoites

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in the liver of an animal as recited in the instant claim 16, and treat malaria as in the instant claim 19. The anti-malarial effective amount would be the same as the specified amount in the instant claims.

3. The rejection for Claims 11-19 under 35 U.S.C. 102(b) as being anticipated by Saxena (PTO-1449) is maintained for reasons of record. The rejection is applicable to new claim 22.

Applicant contends that Carson (submitted with the response) teaches that 'studies of radical cure with prevention of relapses causal prophylaxis, and sporontocidal and gametocytocidal effects must be considered separately from each other, even for the same anti-malarial drug', therefore it is incorrect to assume a particular activity is intrinsic in a compound.

While the anti-malarial compound may have different effects at different stages of the malarial life cycle, the different activities are inherent within the compound. The different modes of action as recited in the instant fail to set a demarcation from the method of the prior art. The court holds that claims directed to mediating a biological pathway are devoid identifiable utility and are therefore not useful. Unless the pathway at issue is critical to treating some condition and the pathway modification and disease treatment are inexorably linked, such pathway modification is devoid of utility. Utility is one of three basic requirements for patentable invention, absent which patent protection is impossible. If the invention fails to achieve the advantage over the prior art asserted by the specification, it is not useful as required by 35 USC 101. *Splendor Form Brassiere, Inc. v Rapid-American Corp.* 187 USPQ 158 (CCPA 1975). In the instant case, the biological pathway, such as blocking the malarial oocyst development as recited in claim 11, is patentable only because it is inexorably linked to the treatment of malaria. Saxena's method of treating malaria in an animal afflicted with malaria with the same CDR1 compound in an anti-malarial effective amount is identical to the instant method wherein the same compound is administered to the same subject. Saxena's method would inherently block the malarial oocyst development as recited in the instant claim 11, combat malaria hypnozoites in the liver of an animal as recited in the instant claim 16, and treat malaria as in the instant claim 19. The anti-malarial effective amount would be the same as the specified amount in the instant claims.

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4. The rejection for Claim 20 under 35 U.S.C. 102(b) as being anticipated by Bhat is rendered moot by the cancellation of this claim.

***Claim Rejections - 35 USC § 112(1)***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A method for blocking malarial oocyst development in an animal prior to formation of malarial sporozoites in the animal as recited in the amended claim 11 is not described in the specification. The rejection is applicable to claims dependent on claim 11. Pages 14-15 cited by the applicant as support for the amendment only describe oocyst in the gut of the mosquitoes and sporozoites in the salivary gland of the mosquitoes, and describe the blocking of the oocyst development while the salivary gland dissections did not show any sporozoites (page 14, last paragraph), which does not equate to the instant 'blocking malarial oocyst development in an animal prior to formation of malarial sporozoites in the animal'.

***Claim Objections***

6. Claim 11 is objected to because of the following informalities: does applicant intend 'A method for blocking....' instead of the instant 'A method blocking....'? Appropriate correction is required.

It is recommended that 'in need thereof' be inserted after 'in the animal' to better define the claim.

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*Conclusion*

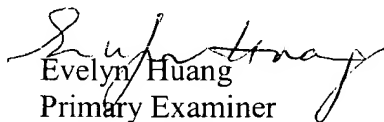
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625

February 14, 2003